

REMARKS

Applicants have submitted a Substitute Sequence Listing and the specification has been amended primarily to ensure the incorporation of appropriate sequence identifiers for all amino acid sequences listed in the specification and claims, pursuant to 37 C.F.R. § 1.821(d). Applicants assert that the changes in the Substitute Sequence Listing and the amendments to the specification do not constitute new matter. Information disclosure statements pursuant to 37 C.F.R. § 1.98(b) have been submitted as part of the prosecution file for this application.

Claims 1-52 and 80-83 are currently under examination for this application. Claims 53-71, 76-79 and 84-87 have been withdrawn from consideration. Applicants have herewith amended claims 1, 3, 4, 6-10, 12, 14, 16, 18, 20-24, 26, 28-31, 32, 34, 36, 38, 40-50, 52, 80, 81 and 83. The amended claims are fully supported by the original application as filed and do not constitute new matter.

1. The Rejection Under 35 U.S.C. §112, Second Paragraph (“Definiteness”), Should Be Withdrawn

The Examiner has rejected claims 1-36, 38, 40, 41, 43-50, 52 and 80-83 for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention, under 35 U.S.C. § 112, second paragraph.

First, the Examiner believes that the reference in claims 1, 21, 29, 41, 43, 45, 47, 49 and 80 to “native” amino acid sequence is potentially confusing and the Examiner offers suggestions as to how that the applicable claims might be amended to render the scope clearly. In response, Applicants appreciate the Examiner’s suggestions and note that the language of the applicable claims has been presently amended such that the term “native” is no longer articulated in the claims and such that the sequences of the claims are more particularly identified.

Second, the Examiner believes that claims 4, 29, 47 and 49 are confusing in the use of the term “C-terminal” with reference to the heptad repeat positions of the claims. Applicants respect the Examiner’s views and note that these claims have been amended in an effort to promote the clarity of the claims. Applicants observe that the “C-terminal” term refers to the latter position (toward the “C” terminus of a sequence) in repeats of motifs, e.g., the second such “e” or “f” in a sample of “efgabcdef” or, as is alternatively recited, “e₁f₂g₃a₄b₅c₆d₇e₈f₉”. Applicants have amended in such a manner that the “C-terminal” term is no longer recited as before and Applicants trust that the claim amendments serve to more clearly render the appropriate residue substitutions referenced by the claims.

Third, the Examiner believes that the use of the claim terms “one or more reactive functionalities” and “amino acid substitution comprising an addition” render claims 6-10, 12, 14, 16, 18, 20, 23, 24, 26, 28, 31, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 81 and 83 vague and indefinite. The Examiner observes, in particular, that while the term “reactive functionalities” is defined in the specification, limitations from the specification are not read into the claims. In response, Applicants note that the claim term “reactive functionalities” has been replaced in the applicable claims with language to more clearly render what appropriate components might constitute an aspect of the synthetic peptides of the invention. Applicants further note that the applicable claims have been amended so as to help distinguish “additions” modifications from “substitutions” and, likewise, to distinguish an initial substitution made within a sequence region from a further “additional” substitution. Applicants believe that the present amendments have addressed the Examiner’s concerns and obviate the present rejection under 35 U.S.C. § 112, second paragraph. Applicants thus ask that the Examiner reconsider and withdraw this rejection.

2. The Rejection Under 35 U.S.C. § 102 Based On Bewley et al. (2002) Should Be Withdrawn

The Examiner rejects claims 1, 4, 11, 17, 19, 33, 41, 47, 49, 80 and 82 as allegedly anticipated by Bewley et al. (2002). Bewley purportedly discloses a synthetic peptide from the HR1 region of HIV-1 gp41 with potent antiviral activity and featuring substitutions at designated (“e” and “f”) heptadic positions.

In response, Applicants note that the applicable claims have been amended to more clearly delineated that which Applicants consider to be the subject matter of the present invention, including articulating a particular sequence and particular polymorphisms thereof of the invention. Applicants have also addressed the length of subject peptides of the present claims such that the peptides of the invention are clearly different and longer than the two 36-mer peptides with narrowly limited and particular substitutions disclosed in Bewley, and as such are clearly not anticipated by Bewley. Applicants thus ask that the Examiner reconsider and withdraw the present rejection under 35 U.S.C. § 102.

3. The Rejection Under 35 U.S.C. 103(a) Based On Bewley et al. (2002) In View Of Barney et al. (1999) Should Be Withdrawn

The Examiner rejects claims 2, 3, 5-10, 12-16, 18-28, 30-32, 34-40, 42-46, 48, 50-52, 81 and 83 under 35 U.S.C. § 103(a) as unpatentable over Bewley in view of Barney et al. (1999). It is believed that one of skill in the art at the time of filing, in view of Bewley and

Barney, would be motivated to modify (e.g., with carrier groups) synthetic peptides of the HR1 region of HIV gp41 and make “conservative” substitutions in the various portions of heptadic repeats therein.

In response, Applicants respectfully disagree with this interpretation, yet note that the claims have been amended, without prejudice, in such a manner that the synthetic peptides of the present invention are different and longer than the two 36-mer peptides described by Bewley. Even should one of skill in the art at the time of the present filing have considered adding carrier groups (or other modifications) to synthetic peptides, such scientists would not have been motivated based on Bewley to seek out and reasonably expect distinct and longer sequences, with or without conservative substitutions thereto, to hold any particular promise as being sequences likely to self-associate as trimers in solution, other than perhaps the mere suggestion that such efforts and manipulations might be “obvious to try.” Such limited teachings are insufficient to render the present subject matter unpatentable under 35 U.S.C. § 103, and Applicants respectfully ask that the Examiner reconsider and withdraw the present rejection in view of the claims as presently recited.

4. The Rejection Under 35 U.S.C. 103(a) Based On Chan (1997) In View Of Barney (1999) Should Be Withdrawn

The Examiner rejects claims 1-52 and 80-83 under 35 U.S.C. § 103(a) as unpatentable over Chan et al. (1997) in view of Barney et al. (1999). It is believed that one of skill in the art at the time of filing, in view of Chan and Barney, would be motivated to modify (e.g., with carrier groups) synthetic peptides of the HR1 region of HIV gp41 and make “conservative” substitutions in the various portions of heptadic repeats therein.

In response, Applicants respectfully disagree with this interpretation, yet note that the claims have been amended, without prejudice, in such a manner that the synthetic peptides of the present invention are different and longer than the 36-mer peptide described by Chan. Even should one of skill in the art at the time of filing considered adding carrier groups (or other modifications) to synthetic peptides, such scientists would not have been motivated based on the art to seek out and reasonably expect distinct and longer sequences, with or without conservative substitutions thereto, to present particular promise as being sequences likely to self-associate as trimers in solution, other than perhaps the mere suggestion that such efforts and manipulations might be “obvious to try.” Again, such limited teachings are insufficient to render the present subject matter unpatentable under 35 U.S.C. § 103, and

Applicants respectfully ask that the Examiner reconsider and withdraw the present rejection in view of the claims as presently recited.

5. The Rejection Under 35 U.S.C. §112, First Paragraph (“Enablement”), Should Be Withdrawn

The Examiner has previously rejected claims 1-36, 41-50 and 52 under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter not described in the specification in such fashion to convey to one of skill in the relevant art that the inventors possessed the claimed invention at the time of filing. Applicants acknowledge and appreciate the Examiner's that this rejection has been withdrawn in response to Applicants' statement.

The Examiner currently rejects claims 1-36, 40-52 and 80-83 under 35 U.S.C. § 112, first paragraph, in that the current specification allegedly fails to reasonably enable a person skill in the art to make or use the invention commensurate in scope with the present claims.

In response, Applicants note that the relevant claims have been amended, in an effort to promote clarity, so as, *inter alia*, to restrict the length and further particularize what modifications (e.g., substitutions) may take place in the sequences of the claims and where in the sequences that these modifications may occur. Applicants have further provided numerous examples in the specification of the different modifications that may successfully be employed to promote trimeric self-association of the peptides in solution, and the claims clearly present that the self-association of the peptides as trimers is key to the scope of the claims and that candidate peptides may be readily tested for such properties. While not each and every such possible amino acid substitution is explicitly listed in the claims or in the specification, the present disclosure offers sufficient guidance such that one of skill in the art would not only be able to readily understand and practice the current invention, but would be able to readily test and choose preferred avenues of pursuit to employ in developing peptides that form trimers in solution. Even while a comprehensive testing of candidates sequences of interest by other scientists to determine trimer formation of those candidates could entail extensive and time-consuming effort, such testing would not require undue experimentation or, in fact, any inventive work upon the part of the scientists, but would entail instead persistent and perhaps meticulous yet essentially routine laboratory practices. Applicants believe that the present amendments to the claims hereby obviate the present rejection under 35 U.S.C. § 112, first paragraph, and Applicants ask that the Examiner reconsider and withdraw this rejection under 35 U.S.C. § 112, first paragraph. Applicants further respectfully request that the Examiner grant an allowance for the pending claims as currently

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Reply to Office communication dated June 6, 2007

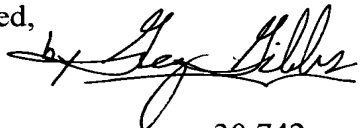
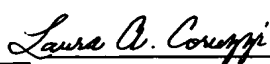
recited, and to rejoin claims 53-71, 76-79 and 84-87 upon the determination that an allowance of claims is proper.

CONCLUSION

Applicants respectfully request entry of the amendment and remarks into the file of the application. Should any issue remain, the Examiner is respectfully encouraged to telephone the undersigned to discuss the same. In the event any additional fee is required, beyond that which is included herewith, please charge the required fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: December 6, 2007

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Enclosures